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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,424	05/30/2001	Anton-Lewis Usala	35626/234826	7082

826 7590 08/13/2004

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,424	USALA, ANTON-LEWIS	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *11,12,14,15,22-24,34,40,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,16-21,25-33,35-39 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of May 14, 2004 is acknowledged. In light of the amendments, this action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888 B1) in view of DeLong et al. (US 2002/0146439) and Obi-Tabot (US6046160).

Gentz et al. is discussed in the previous action. above. Although Gentz et al. teach the use of collagen, the reference does not expressly teach the use of denatured collagen (Applicant's claims 3 and 30). Gentz et al. does not expressly teach the use of a matrix in liquid form or solid form below about 33 degrees Celcius. Gentz also does not expressly teach the use of denatured collagen.

DeLong et al. teach the use of a composition for hair growth in liquid form (para. 206) which is solid at room temperature (para. 167).

Obi-Tabot is discussed in the previous action. Obi Tabot teach the use of denatured collagen.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a liquid form/solid form (at desired temperatures) because DeLong et al. teach the advantageous use of a liquid form of a hair growth composition and a solid state of such (note Applicant's liquid state is between 35-40 degrees, which would encompass DeLong et al.'s solid state at room temperature).

It also would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the denatured collagen of Obi Tabot in the composition of Gentz et al., because Obi Tabot teach the advantageous use of denatured collagen and the use of collagen in a denatured form would be merely routine optimization of one of ordianary skill in the art. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888) in view of DeLong et al. (US 2002/0146439), and Obi-Tabot (US6046160) and further in view of Naughton et al. (US 6372494).

Gentz et al., DeLong et al., and Obi-Tabot are all discussed above. Gentz et al. does not expressly teach the injection of the composition (Applicant's claims 29 and 43).

Additionally, although Gentz et al. generally describe the use of the present invention's compounds in varying amounts, the reference does not expressly teach all the various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine (Applicant's claims 5-6, 8-9, 13, 18-21, 27, and 37-39).

Naughton et al. is discussed in the previous action. Naughton et al. teach the injection of a hair growth composition.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine in the composition for hair follicle stimulation of Gentz et al. because the additional of different amounts of such compounds for desired effects is well within the preview of one of skill in the art and a matter of routine optimization. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants arguments with respect to the art rejections have been carefully considered but are not deemed persuasive of error in the rejection. Applicant has argued that Gentz et al. does not teach that the composition can be in liquid for or solid form at certain temperature. This is not found persuasive, because it is known in the art that matrixes for hair growth can be administered in different liquid/solid states, depending on the desired effect.

Applicant has argued that Naughton et al. does not teach or suggest the present invention because the claimed invention of Naughton et al. is directed to a cell culture medium. This is not found persuasive, because Naughton et al. nevertheless teaches the advantageous use of a

composition (i.e. with EDTA, etc.) which may be injected intradermally. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the hair follicle stimulating formulation of Gentz et al., because Naughton et al. teach the advantageous injection of a hair growth composition with like compounds.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
8/8/04

CHRISTOPHER R. TATE
PRIMARY EXAMINER